

**SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
DECEMBER 04, 2001**

The Environmental Laboratory Advisory Board (ELAB) met on Tuesday, December 04, 2001 at 3:00 p.m. Eastern Standard Time (EST) during the Seventh NELAC Interim Meeting in Arlington, VA. The meeting was led by its chair, Zonetta English of Louisville and Jefferson County MSD. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The meeting's agenda is given in Attachment C. David Friedman's Presentation is given in Attachment D. Minutes prepared by ELAB for their May 24, 2001 meeting are given in Attachment E. The purpose of the meeting was to address items of importance identified in the meeting agenda.

INTRODUCTION

The meeting was called to order by ELAB's Designated Federal Officer (DFO), Edward Kantor of the U.S. Environmental Protection Agency (EPA), who then introduced the Chairperson, Zonetta English. After the introduction of ELAB members, Ms. English welcomed the attendees and reviewed the minutes from the May 24, 2001 meeting, which were approved as submitted, with no opposition.

SUBCOMMITTEE REPORTS

Performance Based Measurement Systems (PBMS) Subcommittee

Harry Gearhart reviewed the recommendations for the PBMS Subcommittee from the May 24, 2001 ELAB minutes. These recommendations, adopting the concept of PBMS into the Standards, will be presented at the Quality Systems meeting.

REVIEW OF ELAB RECOMMENDATIONS

Ms. English proposed that due to the issues of New Business, members simply review the previous recommendations and discuss those issues that are still active at the next teleconference.

NEW BUSINESS

Restructuring of NELAC

David Friedman, of the Environmental Protection Agency, began his presentation with some background information on NELAC. Over the last decade, NELAC was born and is now in its teen years, moving towards adulthood. To this end, greater participation by the private sector is sought, and the ability to accomplish things that currently it cannot. For example, there is no mechanism in place to approve new proficiency testing oversight bodies with which to expand the program to include the analyte and matrices currently not handled, and the ability to achieve financial stability. To help NELAC address these issues, EPA has contracted to do a feasibility study, which will be completed by April. Some things this study is addressing are:

- Evaluate current status of NELAC program
- Analyze unmet needs of the program
- Compare needs to realities
- Evaluate feasibility and viability of a non-profit organization to support NELAC program

During the recent strategic planning session, in which representatives from all stakeholders participated, brainstorming sessions were held on developing mission, vision, organizational structure, and critical challenges. Of these, three primary challenges emerged:

5. Current structure not appropriate;
 - a. Cannot utilize non-federal sources of funding.
 - b. Does not maintain sufficient distinction between government and non-government roles.
 - c. Prevents program from doing things that it needs to do, such as approving PTOB's, training programs, web site development and operation.
6. Self-Sufficiency;
 - a. EPA does not want to be the sole financial supporter of the program.
 - i. No statutory authority (except for drinking water).
 - ii. Agency does not have statutory authority to accept funding or charge a fee-for- services to fund program.
 - iii. Agency facing a decreasing budget.
7. Strategic Vision/Action Plan;
 - a. EPA Deputy Administrator has requested that the accreditation community develop a strategic plan and a timetable for implementing the plan..
 - b. EPA Deputy Administrator wants NELAC to begin to address and implement structural changes as soon as possible.

The strategic planning meeting resulted in a number of options on how NELAC might be structured, most of which were unacceptable. The plan people felt the most comfortable with was to split NELAC into a Standards Development Group, with full stakeholder participation, which would be fully separate from the Standard Adoption Group. In addition, the not-for-profit organization would not be able to be involved in governmental functions. The particular details for creating this still have to be developed. The planning session also listed some roles and responsibilities for these bodies, which need further development. This restructuring will need to be in compliance with Federal Advisory Committee Act (FACA) and Unfunded Mandate Act. The Standards Development Group will need to be run by an independently established organization. The not-for-profit organization cannot perform roles that appear to be governmental functions. In order for the program to have credibility, it would benefit from using existing groups that already have credibility, to help develop its Standards. It would further benefit from having contractual relationships with federal entities and not-for-profit organization to help with funding.

The issue was then opened to discussion from the floor. It was suggested that in considering the proposed options, the organization should not omit looking to Congress , which already has spent a lot of time and effort and has some structures in place, namely the National Institute for Standards and Technology (NIST), which has the authority to coordinate laboratory accreditation in the United States. It was suggested working with NIST, rather than duplicating the infrastructure already in

place. Furthermore, as NIST already has a not-for-profit organization in place, National Cooperation for Laboratory Accreditation (NACLA) whose purpose is lab accreditation, NELAC could work with this not-for-profit organization rather than start up a new one. In response, Bob Wyeth pointed out that the Executive Director from NACLA was present at the strategic planning session and that these suggestions were being considered. Several more attendees voiced their support in using existing standard setting bodies.

Silky Labie asked for clarification concerning the division of Standards Development Group and the not-for-profit organization, as she understood the not-for-profit organization being part of the Standards Development Group. Mr Friedman responded that the Standards Development Group has to be independent of the Standards Adoption Group. If the not-for-profit organization is involved with both groups, they are then no longer viewed as independent, and it is vital that they be separate. Ms. Jeanne Hankins commented that NACLA praised NELAC in its work of coordinating several different government entities to use the same type of standards, based on international standards. An attendee asked for clarification as to the function and need for a not-for-profit organization. Chairperson English responded that under the terms of the contract, those involved in the contract are not allowed to answer this question.

Chairperson English asked if Dr. Kenneth Jackson would respond to previous questions asked as to what the reason was for the planning session. Dr. Jackson said one of the purposes was to increase the involvement of the private sector. One option was to make the Standards Development Group part of ELAB or a FACA involvement. That was rejected because any FACA committee reports to EPA, which would give EPA veto power over any standard that is put together before it is presented to the Conference for vote. The only other alternative was to divide NELAC into Standards Development and Standards Adoption, with Standards Development totally independent of EPA. A not-for-profit organization is brought into the picture because there must be a way of doing this. The functions of the not-for-profit organization were considered, one of which would be running the Standards Development Group. However, other options can be considered. The not-for-profit organization has to take over some of the administrative functions of NELAP, as that has been in the works now for several years. Another function of the not-for-profit organization would be to help support NELAC, which may remain as the Standard Setting body. The same not-for-profit organization may not be able to perform all three functions.

Dr. Harry Gearhart added that the EPA management has expressed the opinion that the existing organizational structure of NELAC does not appropriately support the level of private sector participation, both in document generation and deliberation. Secondly, there is a need that has always been voiced by EPA for NELAC to become financially sustainable. Therefore there is a need to revise the structure to meet those needs. Mr. Friedman added that under current governmental rules, organizations of federal, state, and tribal regulatory officials can meet to develop and adopt policies, with no restraints. The way NELAC was originally set up, governmental employees were going to be responsible for developing standards, adopting standards, and running the program. The private sector had no major role in that. At the behest of the private sector, EPA then established ELAB, to give the private sector a bigger voice in the process. Over the years, the private sector has been more involved in the standard setting. This resulted in NELAC no longer being just a federal, state, and tribal body. That is why there is now a need for separation. The not-for-profit organization comes into play to relieve EPA of things that are not governmental and that EPA does not have to

do. EPA can fund not-for-profit organizations in the form of grants, which it cannot do for a for-profit organization.

Louis Johnson commented that one of the purposes of the planning session was to talk about a strategy for NELAP in 2006. He also mentioned that it was important to keep Accrediting Authorities as an active group in the Standards development. Mr. Friedman responded that although there will be separate organizations; however, those involved in the Standards Adoption body can still be involved in Standards Development.

Mr. Wyeth asked that further details be provided to this Advisory Board as to why the process is now necessary and what the issues are that ELAB is to address. The only way to be certain this process is being done appropriately and effectively is to know exactly what issues the EPA has brought to the table which have started this process. He would like to see written opinion as to why a structure that was acceptable some years ago is no longer acceptable and why some of these options are going to be problematic. Until such time as more clarity is provided as to why the originally approved charter is no longer acceptable, it will be extremely difficult for this Advisory Board to take effective action. Therefore, EPA and the Office of General Council must provide in writing what they are opposed to, before any action can be taken. An Accrediting Authority also voiced his opinion that a written legal opinion must be obtained prior to making any changes in the structure of NELAC.

Chairperson English asked if there were any further questions regarding this issue or need for clarification on the charge for ELAB. Mr. Gearhart suggested requesting a written articulation from EPA in order to facilitate an appropriate, comprehensive, and effective response, which would also act as a benchmark in order to define success. Mr. Jerry Parr recommended the following:

1. Send letter to the Administrator requesting key information, a clear charge for what is expected to be done, and a timetable for getting it done; and
2. In the same letter, recommend that EPA request that NELAC form a special committee to develop recommendations surrounding restructuring and self-sufficiency.

An attendee suggested that ELAB take the charge from EPA and this opportunity to solicit testimony from each of the NELAC committees and Accrediting Authorities as to what the impediments are for their success under our current structure, so that it can be turned into a successful structure for all parties involved. Another attendee mentioned that this was a very confusing session and that it may be a bit premature for ELAB to act on this as key information is still lacking. He is also confused as to what exactly the goals are. Chairperson English responded that ELAB had been charged with the issue of restructuring NELAC and that that was the reason for this discussion.

Mr. Parr also asked opinions of NELAC Board of Directors whether ELAB should consider forming a joint working group with Board members or with the Transition Committee, or what thoughts they might have for this Board to recommend. Ms. Labie responded that she would like to see formed a subcommittee of ELAB or the Transition Committee to look into this with greater detail and provide more guidance. When asked what the goal of a timeline would be, she responded originally it was by NELAC 8; however, now it appears it may be possible to take more time. Mr. Kantor pointed out that a federal advisory committee cannot join with a non-federal advisory committee, according to

FACA guidelines. Ms. Hankins stated that the concerns expressed today should be conveyed to the Administrator, along with a timeline and general description of what the process might be. Also, in addition to the Transition Committee, the Program Policy and Structure Committee should have input and have a proposal ready for the Administrator. Ms. Hankins suggested advertising in the Federal Register, having a DFO present, and having an open meeting. This would fulfill FACA requirements. Mr. Parr suggested that ELAB could give this issue over to the Transition Committee, which could set up a subcommittee of any membership and that committee could report to ELAB. Chairperson English suggested to set up a meeting between Program Policy and Structure Committee and the Transition Committee, sending due notice to set up a teleconference to discuss this issue further. In addition, ELAB is to form a subcommittee to draft a letter that includes a problem statement and a time table. Mr. Parr moved to have an ELAB subcommittee start this week to draft an appropriate letter to send to the EPA Administrator which captures all the discussion points. He also moved to schedule ELAB to meet to review this draft letter. Notice of this meeting needs to be published in the Federal Register 15 days prior to the meeting date, which will be the second Wednesday of January. This motion was seconded and unanimously approved. Dr. Mark Marcus recommended that ELAB get back to regularly scheduled teleconferences every two months. Chairperson English will e-mail members to ascertain the best time for calls.

Mr. Parr requested EPA to request someone from NELAC to provide a report to ELAB at some future teleconference on any effort they are making. However, Mr. Kantor interjected that as this must be accessible to the public, he will post this in the Federal Register Notice.

Other Business

Ms. Hankins reported that she has provided some language to the Program Policy and Structure Committee to incorporate Indian Tribes as voting members of NELAC. If an Indian Tribe has either regulatory responsibilities or accreditation duties, that upon receipt of their request they be included as a voting member of NELAC. As voting members, they would be allowed to designate one individual to serve in the House of Representatives and another individual to vote in the House of Delegates. Since there has been no prior recommendation from ELAB on this issue, she asked the Board to consider the language proposed and make a recommendation to EPA. Mr. Parr moved that the ELAB chair draft a formal letter and send it to the EPA. This motion was seconded and unanimously approved. Chairperson English accepted the assignment of drafting the letter.

Dr. Jackson brought up the issue of states that have two-tier systems of accreditation. A major problem is the limited participation of small laboratories in NELAC. An attempt to address these issues was always made during the revisions of the Standards, but the feeling is that there has never been enough input from small laboratories. He suggested that ELAB consider forming a work group to involve small laboratories in looking at the Standards to see if anything else can be done to increase their involvement. Mr. Parr requested that this be added to the action items. Mr. Parr volunteered to review previous action items and update all the open ones. All members offered to participate in updating these items.

There being no further business to discuss, the meeting was adjourned.

ACTION ITEMS
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
DECEMBER 04, 2001

Item No.	Action	Date to be Completed
1.	Ms. English proposed that members simply review the previous recommendations and discuss those issues that are still active at the next teleconference.	1/09/02
2.	Mr. Parr moved to have an ELAB subcommittee start this week to draft an appropriate letter to send to the EPA Administrator that captures all the discussion points.	ASAP
3.	Mr. Parr moved to schedule ELAB to meet to review this draft letter. Notice of this meeting needs to be published in the Federal Register 15 days prior to the meeting date, which will be the second Wednesday of January..	
4.	Chairperson English will e-mail members to ascertain the best time for calls.	
5.	Mr. Kantor will post in the Federal Register Notice a report on the progress made by the committees.	
6.	Chairperson English will draft a letter to the EPA recommending that Indian Tribes be voting members of NELAC.	ASAP
7.	Dr. Jackson suggested that ELAB consider forming a work group to get the involvement of small laboratories to look at the Standards to see if there is anything else that can be done to increase their involvement.	
8.	All members volunteered to review previous action items and update all the open ones.	ASAP

PARTICIPANTS
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
DECEMBER 04, 2001

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A r l i n g t o n , V A

Attachment C

Tuesday, December 4, 2001

3:15 pm - 6:00 pm ELAB Meeting

Salons A,B

Roll Call and Introductions

Ms. Z. English

*Reading and Approval of Minutes
(Meeting Summary 05/24/01)*

Reports from Subcommittees

Review of ELAB Recommendations

New Business
- Restructuring of NELAC
- Other

Announcements

Closing

Ms. Z. English



Attachment D

ENVIRONMENTAL LABORATORY ADVISORY BOARD

**National Environmental Laboratory Accreditation Conference
Seventh Interim Meeting
December 04, 2001**

**Organization & Structure Issues
by
David Friedman
Environmental Protection Agency
Washington, DC
December 04, 2001**

Organization & Structure Issues

David Friedman

Environmental Protection Agency

Washington, DC

December 4, 2001

Moving NELAC Toward Adulthood

- Opportunity for greater participation by the private sector
- Opportunity to fulfill roles not being addressed currently, for example PTOB for non-WS/WP
- Opportunity to have a financial stability

Feasibility Study

- Evaluate the current status of the NELAC program
- Analyze the needs of the NELAC program
- Compare the needs to realities
- Evaluate the feasibility and viability of a non-profit organization in supporting NELAC

Futures Workshop

- Participation by representatives from all stakeholders
- Brainstorming sessions on mission, vision, organizational structure, and critical challenges
- Ranking of critical challenges

Challenges to Address

- Current structure not appropriate for long-term development of program.
- Program needs to be self-sufficient and not be so reliant on EPA for funding.
- EPA management has asked that a strategic vision and plan/timetable of action be developed.

Current Structure Not Appropriate

- Cannot utilize non-federal sources of funding
- Does not maintain sufficient distinction between gov't and non-gov't roles
- EPA has a larger role than it intended to play
- Doesn't fully utilize expertise of private sector
- Prevents program from doing things that it needs do, for example:
 - Approving PTOBs and Training Programs
 - Web Site development and operation

Self-sufficiency

- EPA does not want to be, nor can we be, the sole financial supporter of the program
 - no statutory authority (except for drinking water)
 - Agency does not have statutory authority to accept funding or charge a fee-for-services to fund program.
 - Agency facing a decreasing budget

Strategic Vision/Action Plan

- EPA Deputy Administrator has requested that the accreditation community develop a strategic plan and a timetable for implementing the plan.
- EPA Deputy Administrator wants NELAC to begin to address and implement structural changes as soon as possible.

Proposed Options

1. NELAC = FACA
2. NELAC with Membership Restrictions
3. Total Privatization
4. Statutory Authorization for NELAC
5. Status Quo with EPA Management Review Policy
6. Independent Standard Development Body
+ NELAC + NELAP + Not-for-Profit

Option 6 (modified)

Standards Development Groups
(Full Stakeholder Participation
And Voting Rights)

Standard Adoption Group
(States, Feds, Tribes)
NELAC



EPA
Approve AA
NELAP



States
Accredit Labs

Not-for-Profit

Roles

- Sponsor NELAC Meeting
 - Development
 - Adoption
- Teleconference Arrangements
 - Development
 - Adoption
- Scribe Support
- Standards Publication
- Documentation Maintenance
- Website
- NELAP Database
- Evaluation NELAP AAs
- Accredited State & EPA Laboratories
- Approve PTOBs
- Approve Lab Assessor Trainers
- PT Database Maintenance
- Needs Survey
- Training
- Conflict/Resolution
- NICE Line

Things to keep in mind ...

- Appearance
 - Standards Development Groups needs to be run by an independently established organization
 - Not-for-Profit cannot perform roles that appear to be governmental functions
- Credibility
 - Benefit of existing standards development partnership
 - Benefit of contractual relationship between Federal entities and Not-for-Profit



Attachment E

ENVIRONMENTAL LABORATORY ADVISORY BOARD

**National Environmental Laboratory Accreditation Conference
Seventh Interim Meeting
December 04, 2001**

**May 24, 2001
Minutes**

**SUMMARY OF THE
ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING
MAY 24, 2001**

The Environmental Laboratory Advisory Board (ELAB) met on Thursday, May 24, 2001, at 2:00 p.m. Mountain Daylight Time (MDT) during the Seventh NELAC Annual Meeting in Salt Lake City, UT. The meeting was led by its chair, Dr. Wilson Hershey of Lancaster Laboratories, Inc. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The meeting's agenda is given in Attachment C. Minutes prepared by ELAB for their January 9, March 6, and April 24, 2001 meetings are given in Attachments D, E, and F respectively. *The purpose of the meeting was to address items of importance identified in the meeting agenda.*

INTRODUCTION

The meeting was called to order by ELAB's Designated Federal Officer (DFO), Dr. Steven Billets of the U.S. Environmental Protection Agency (EPA). Following an introduction of ELAB members, Dr. Billets noted that ELAB's charter will expire at the end of July 2001. Dr. Billets also noted that the paperwork necessary to recharter the U.S. EPA-sponsored advisory committee established under the Federal Advisory Committee Act (FACA) for another two-year term has been completed and is on its way to the agency's Deputy Administrator. He then turned the meeting over to Dr. Hershey, who welcomed attendees and reviewed the meeting agenda. The minutes from ELAB's January 9, March 6, and April 24, 2001 meetings were reviewed. Dr. Hershey noted that ELAB prepared their own minutes for these meetings and that the minutes have not yet been posted on the NELAC Website. He indicated that the minutes from the three meetings would be incorporated into the minutes from this meeting at NELAC 7. The January 9 and April 24 minutes were accepted as written. The March 6 minutes were accepted pending correction of a minor typographical error. The status of action items from the three meetings was also reviewed. Dr. Hershey directed ELAB's attention to the March 6 minutes in which he was asked to invite Mr. Robert Graves (U.S. EPA) and Ms. Reenie Parris (National Institute of Standards and Technology - NIST) to address ELAB on May 24. He explained that Mr. Graves and Ms. Parris had been invited to the meeting but had declined. Dr. Hershey also noted that the three recommendations from ELAB's April 24 meeting were printed on the back of the May 24 meeting agenda. He pointed out that the NELAC Board of Directors (BoD) is already working on the third recommendation, which reads as follows:

ELAB recommends that NELAC establish a policy as to when it will develop standards for new testing areas such as source emissions, field sampling, etc. That policy should specify the number of requests necessary from federal agencies or accrediting authorities so that committees have a clear mandate to develop new standards.

UPDATE ON PROFICIENCY TESTING (PT) ACTIVITIES

Ms. Barbara Burmeister, NELAC PT Committee chair, presented an update on her committee's efforts to identify and solve problems arising since the implementation of the NELAC PT program. She

noted that the committee has been working diligently, holding two face-to-face committee meetings and inviting NELAC stakeholders (laboratories, accrediting authorities, and PT providers) to join them in addressing the issues. Ms. Burmeister summarized the issues as follows:

Resolved

1. Mechanism to fast-track reinstatement after PT failures and expansion of field of accreditation - The NELAC PT Committee proposed changes to the NELAC Standard to accomplish this.
2. Standardization of the PT evaluation report format - The NELAC PT Committee proposed changes to the NELAC Standard to accomplish this.
3. Consistent reporting and scoring of PT data - The NELAC PT Committee developed a list of Frequently Asked Questions (FAQs) to clarify this process. Some inconsistencies exist and will be addressed. The committee will work with the U.S. EPA to revise their National Standards for Water Proficiency Testing Criteria Document.

To Be Addressed Before NELAC 7i

4. Problems with acceptance criteria - The NELAC PT Committee will utilize a PT subcommittee to identify current acceptance limit criteria that don't seem to be working. The NELAC PT Committee will also create a permanent subcommittee of technical experts to evaluate current acceptance criteria and monitor pass/fail performance.

Ongoing Unresolved Issue

5. Need a Proficiency Testing Oversight Body (PTOB) and additional Proficiency Test Provider Accreditors (PTPAs) for analytes beyond NIST's scope of accreditation

Following Ms. Burmeister's presentation, the members of ELAB asked if the NELAC PT Committee needs any assistance from ELAB. Ms. Burmeister responded that the PT Committee does not need assistance at this time contingent upon their ability to create a permanent subcommittee of experts through NELAC. She noted that the PT Committee may need input from ELAB regarding who should serve on the subcommittee. In subsequent discussion of PT issues it was noted that the NELAC PT program is working well with only minor start-up problems. There are significant problems, however, with non-NELAC states in regard to differing state requirements for analytes, PT schedules, etc. These issues of scope and timing increase the number of PT samples that states must analyze. There is no mechanism in NELAC to deal with non-NELAC states. There was significant discussion from the floor in regard to the private sector laboratory's cost to buy PT samples to satisfy NELAC PT requirements, non-NELAC state PT requirements, Department of Defense (DoD) PT requirements, and client PT requirements. There was also discussion of PT failure issues that have nothing to do with normal laboratory data quality issues, such as volume dilution requirements arising from differences between PT samples and realworld samples and clerical data reporting errors. A PT provider made three suggestions as to ways that ELAB can assist in the resolution of these problems:

1. ELAB could make recommendation that a uniform scope of accreditation (especially for NELAC laboratories) be implemented as soon as possible.

2. ELAB could make recommendation that non-NELAC states review NELAC PT program before developing their own programs.
3. ELAB could encourage states to set only PT requirements rather than a fixed timeframe for PT sample analysis.

Considerable discussion ensued in regard to whom ELAB should make such recommendations, how ELAB can provide information to non-NELAC states, and of whether such recommendations fall within the scope of ELAB's charter. There was some interest in preparing a position (white) paper. The issue was taken under advisement for discussion in the one teleconference remaining before the expiration of ELAB's charter.

SUBCOMMITTEE REPORTS

Performance Based Measurement Systems (PBMS) Subcommittee - Dr. Harry Gearhart, Chair

Dr. Gearhart presented a brief recap of recent ELAB activities on PBMS and a summary of the NELAC Quality Systems Committee PBMS subcommittee work product presented in the Quality Systems Committee meeting on May 22, 2001. Dr. Gearhart reported that ELAB presented the conceptual straw model for PBMS implementation at NELAC 6i. The NELAC Quality Systems Committee then accepted the task of developing a "Standard Implementation Model for PBMS." Following NELAC 6i, the NELAC Quality Systems Committee formed a PBMS subcommittee to integrate PBMS concepts into proposed standard language and to develop a work product for consideration by the Quality Systems Committee. The subcommittee set a tentative deadline for completion of draft revisions of Chapter 5 and supporting Appendices C and D1 for presentation to the Quality Systems Committee as a "work-in-progress" report at NELAC 7. The presentation was intended to facilitate discussion and elicit input from NELAC stakeholders for the benefit of the Quality Systems Committee in moving forward with the work product. Dr. Gearhart summarized the highlights of the subcommittee work product presented on May 22 as follows:

1. PBMS concepts were integrated into the language of Chapter 5 as laboratory practice and policy, virtually eliminating the phrase "performance based measurement system" and its related acronym "PBMS."
2. The client's role was articulated and clarified in Chapter 5.
3. The ELAB straw model concepts of method use, method selection, and method evaluation were carried forward in Chapter 5.
4. Improvements were suggested regarding instrument calibration and methods manual structure.
5. Appendix C described a proposed model for initial method evaluation based on "representative matrices." Various primary source material was referenced.

6. Appendix D detailed ongoing method evaluation steps to determine and document sources of uncertainty relating to actual sample matrices and system influences.

Dr. Gearhart also summarized significant audience comments concerning the work product as follows:

1. There exists a strong sense that a tiered approach, which differentiates between agency-mandated methods and other alternatives, should be considered versus a uniform approach for initial evaluation requirements.
2. The rationale for further modifications to the calibration section was questioned.
3. Clarification was requested on what training exists for the Method Quality Objective (MQO) approach. Mr. David Friedman, U.S. EPA, provided an answer.
4. Method Blank acceptance criteria were questioned.
5. A concern was raised for alternative method selection and the Daubert principles of data admissibility and defensibility. This continues to be an issue of concern, especially to individuals in regulated entities.
6. Mandated method batch quality control (QC) should be preferentially followed.
7. Clarification was requested regarding client approval in the methods selection process. The clarification was provided by Mr. Jerry Parr.
8. Reconsideration of the standard's definition of matrix was recommended.

Dr. Gearhart noted that the subcommittee perceived the following needs for improvement in the model as it currently exists:

1. Revisiting the "matrix type" definition in the NELAC Standard
2. Reevaluation of an appropriate or preferable tiered approach to the initial evaluation
3. Clarification of hierarchy of batch QC requirements in mandated methods
4. Input from persons with expertise in statistics relative to calculation of uncertainty, especially for the initial evaluation process
5. Appropriate incorporation of Analysts Initial Demonstration of Competency in Chapter 5 or elsewhere in the NELAC Standard

In closing Dr. Gearhart summarized several recommendations made to the NELAC Quality Systems Committee as follows:

1. Consider the necessary steps in continuing to revise the NELAC Standard.
2. Provide recurring training for accrediting authority assessors (start at NELAC 8?).

3. Make a deliberate effort to improve communication, both within NELAC and with external stakeholders.
4. Consult with the NELAC Chair to form an implementation subcommittee. (It was acknowledged that the formation of an implementation subcommittee may be outside the scope of the Quality Systems Committee.)

In subsequent discussion of Dr. Gearhart's subcommittee report, Mr. Parr stressed the subcommittee's attempts to eliminate the phrase "performance based measurement system" and its related acronym "PBMS." He suggested that ELAB encourage NELAC committees to remove the phrase from their chapters. It was also noted that the integration of International Organization for Standardization (ISO) Document 17025 into Chapter 5 is occurring as a parallel activity. It will be necessary to revisit Chapter 5 in regard to PBMS after the integration of ISO 17025. It was suggested that the subcommittee has served its purpose to generate discussion of the issue. The ELAB PBMS subcommittee is now inactive.

Air Source Emission Task Team (ASETT) - Dr. Allen Verstuyft, Chair

Dr. Verstuyft reviewed the first two recommendations printed on the back of the May 24, 2001 meeting agenda as follows:

ELAB recommends that NELAC delay adoption of accreditation standards for stack testing for two years. ELAB recognizes the Field Activities Committee's concern for the quality of source testing and reporting data. In lieu of accreditation under the NELAC process, the states and EPA are, of course, free to promulgate regulations as they deem appropriate.

ELAB recommends that ASETT and the Measurement of Source Emissions (MSE) Subcommittee be disbanded as subcommittees of ELAB and the NELAC Field Activities Committee, respectively.

Dr. Verstuyft explained that the two recommendations had been discussed in ELAB's March 6 and April 24, 2001 teleconferences. He also noted that the Source Evaluation Society, the state of Louisiana, and the American Society for Testing and Materials (ASTM) Committee D2 have expressed an interest in examining the stack testing issue during the two-year delay in adoption of stack testing standards. There was minimal additional discussion of the issue from ELAB or the floor.

METHODS AND DATA COMPARABILITY BOARD (MDCB) RECOMMENDATIONS

Mr. Parr explained that the MDCB is a FACA committee focused on ambient water quality monitoring. MDCB's membership draws heavily from state and federal agencies with major participation from the U.S. Geological Survey (USGS) and U.S. EPA. Mr. Parr indicated that he has two goals concerning MDCB. He would like to see ELAB investigate synergy with MDCB so that the two committees can

work together toward common goals. He would also like to see ELAB endorse the four recommendations set forth in MDCB's white paper on the accreditation of federal laboratories for water quality and monitoring. The recommendations outlined in the white paper's executive summary are as follows:

1. All federal laboratories (and commercial laboratories employed by federal agencies) performing analytical water testing, as part of compliance or ambient monitoring programs, should be accredited under a recognized program, in order to better establish comparability of data.
2. The National Environmental Laboratory Accreditation Program (NELAP) is the MDCB's recommended program, because NELAP adequately meets (or is taking measures to meet) the broad needs of the majority of federal laboratories performing water testing.
3. For NELAP to serve as a satisfactory accrediting program for federal laboratories, NELAP needs to continue its efforts to:
 - Obtain more state participation and reciprocity
 - Address standards for ambient monitoring, field sample collection, and field measurements
 - Promote the development of PBMS implementation
4. Federal agencies should consider seeking to become an accrediting authority for their own laboratories under NELAP.

When the issue was opened to discussion from the floor, it was noted that recommendation #3 has already been accomplished by ELAB. There were several suggestions about combining the remaining recommendations into one recommendation. In response a representative from one of the federal agencies in attendance urged ELAB to delay endorsing recommendation four. Noting that most federal laboratory work has been privatized and that few federal agencies are performing their own laboratory work, she suggested that it would be resource-intensive and a waste of time for all agencies other than U.S. EPA to become accrediting authorities in order to accredit their own laboratories. It was generally agreed that the time is right for integration between ELAB and MDCB. An attendee directed ELAB's attention to the portion of the white paper that mentions ELAB specifically and provides a list of topics about which MDCB and ELAB should be communicating. There was discussion of interaction between the two FACA committees with the suggestion that either a member common to both or one member from each should act as liaison(s). After moderate discussion, it was suggested that Mr. Parr serve as ELAB liaison to MDCB and that Dr. Barton Simmons of the California EPA serve as MDCB liaison to ELAB. Mr. Parr and Dr. Simmons indicated their willingness to serve in this capacity. Since at least one member of ELAB requested additional time to review the MDCB's white paper, it was decided that ELAB would consider this idea at their next teleconference. After considerable discussion, Mr. Parr indicated that he would customize specific issues of overlap between ELAB and MDCB and draft a specific recommendation or recommendations for discussion at the next ELAB teleconference.

COMMENTS ON PROPOSED CHANGES TO THE NELAC STANDARD

Dr. Hershey pointed out that the NELAC Quality Systems Committee has revised the blank criteria in Chapter 5, reducing the four criteria to two. He suggested that “data quality objectives” in the second of the two criteria should be changed to “method quality objectives.” After minimal discussion, the issue was deemed not pressing. Mr. Parr noted that he had gotten a sense that most NELAC stakeholders are pleased with the language proposed for vote at NELAC 7. After moderate discussion it was moved, seconded, and approved unanimously that

ELAB endorse all proposed changes to the NELAC Standard and recommend to the NELAC community that they vote to adopt them.

Dr. Hershey then opened the issue to discussion from the members of ELAB. In discussion of the integration of ISO 17025 into Chapter 5, ELAB noted that a straw poll conducted in the NELAC Quality Systems Committee meeting favored incorporating the ISO 17025 language verbatim rather than by reference. It was suggested that incorporating the language verbatim creates problems with copyright issues and with attempts to keep the standard current. It was also noted that U.S. EPA is paying a copyright fee for the use of ISO Guide 25 but not for ISO 17025. In response Mr. Frederic Siegelman, chair of the NELAC Quality Systems Committee, reported that participants in the straw poll had indicated that they wanted a standard consisting of one document organized like ISO 17025 and including the ISO 17025 text. In response to questions about how the ISO 17025 text would be incorporated into Chapter 5, Mr. Siegelman shared his proposed strategy. He reported that the Quality Systems Committee has created a working document that includes all of Chapter 5, ISO Guide 25, and ISO 17025 text because they anticipated having to pull some language from the document. Outdated ISO Guide 25 language will be removed as needed. Mr. Siegelman proposed putting a marker after all ISO 17025 clauses so that they can also be pulled and incorporated by reference if necessary. He then proposed selecting the most appropriate language from all the sources included in the working document to produce the best standard. Mr. Siegelman noted that he anticipates that the current appendices will remain as appendices and proposed pulling some information (e.g. PBMS) into additional appendices. In closing he asked for input from NELAC stakeholders. The issue was opened to discussion from the floor. An individual who had participated in the NELAC Quality Systems Committee’s straw poll earlier in the week reported that not everyone participating in the straw poll realized that incorporation of ISO 17025 into Chapter 5 implied verbatim incorporation. She reported that she had understood the two options presented in the Quality Systems Committee meeting to be:

1. two documents - ISO 17025 integrated into Chapter 5 by reference only with no incorporation of ISO 17025 text, or
2. one document - requirements of ISO 17025 incorporated into Chapter 5, not necessarily verbatim

There was considerable discussion from the floor of proposed changes to Chapter 1 of the NELAC Standard (Program Policy and Structure). Noting that Chapter 7 (Field Activities) would not be put up

for a vote at NELAC 7, an attendee suggested that a number of proposed changes to Chapter 1 parallel Chapter 7 and should be reexamined or removed. Specific sections cited were 1.1.3 (reference to Chapter 7), 1.4.2.1 (scope of NELAC includes environmental sampling and testing), 1.8.1 (scope of accreditation to include field sampling), and 1.8.4 (section in its entirety added to be commensurate with adoption of Chapter 7). In response, Dr. Kenneth Jackson, chair of the NELAC Program Policy and Structure Committee, reported that most of these issues have been resolved. Dr. Jackson noted that section 1.8.1 would be withdrawn by the committee if Chapter 7 were not put up for a vote. He also noted that the other sections merely pertain to the Field Activities Committee's charge and do not depend upon the adoption of Chapter 7. Audience members expressed a lingering concern that a change in the scope of NELAC has not been effectively communicated to affected parties in both the regulatory community and industry. Citing Section 1.4.2.1 as an expansion of NELAC from laboratory to non-laboratory entities, an attendee asked if this expansion was authorized in the original Federal Register notice for NELAC. Ms. Jeanne Hankins, NELAP Director, noted that the Federal Register notice was not an authorization and explained that the previous FACA Committee, the Committee on National Accreditation of Environmental Laboratories (CNAEL), had been requested by U.S. EPA to include sampling. Mr. Parr noted that language reflecting the inclusion of sampling was actually proposed and adopted several years ago as the second sentence of Article 1 of the NELAC Constitution. ("The purpose of the organization is to foster the generation of environmental laboratory data of known and documented quality through the development of national performance standards for environmental laboratories and other entities directly involved in the environmental field measurement and sampling process.") Dr. Jackson further explained that it has always been the intent of the NELAC Standard to include sampling and that nothing more will happen in that regard until Chapter 7 is adopted. Many audience members noted that a significant number of data errors are sampling issues. Laboratory representatives expressed support for the language in Chapter 1.

It was generally agreed that not enough has been done to reach out to stakeholders. As a result of discussions on the issue, it was proposed that NELAC provide clarification of its intent to address non-laboratory entities through a November 2001 Federal Register notice. Ms. Hankins pointed out that NELAC is a voluntary organization separate from U.S. EPA and, therefore, cannot utilize the Federal Register mechanism. Members of ELAB suggested that ELAB recommend that both the NELAC BoD and U.S. EPA seek ways to reach out to other organizations to indicate that the scope of NELAC as defined in the NELAC Constitution includes non-laboratory organizations. After moderate discussion of this suggestion, Mr. Parr and Dr. Verstuyft indicated that they would wordsmith the language of the formal recommendation and the issue was deferred to ELAB's next teleconference.

POLICY ON ACCELERATED IMPLEMENTATION OF THE NELAC STANDARD

At Dr. Hershey's request Ms. Hankins reviewed the NELAC policy on accelerated implementation of the NELAC Standard. She reported that copies of the policy on implementation would be provided at the NELAC 7 voting session and explained that the policy stipulates that every current NELAP accrediting authority must be capable of meeting the requirement of the standard for immediate implementation. She agreed that an implementation date should be included on the document. Ms. Hankins reviewed the process for implementing a new standard. The first step in the process is preparation of an amendment to the standard that affects the approved standards from the previous two

years. The second step in the process consists of posting a notification on the NELAC Website with a spatial link to the standards. The final step consists of written notification to the NELAP accrediting authorities who will cascade the notification down to their laboratories. There was considerable discussion from the floor on implementation policy. A representative from the state of Florida reviewed his state's current regulatory timetable, noting that any standard applicable to laboratories is adopted by rule and that his state will never be able to implement a new standard "immediately." He pointed out that the effective date of the NELAC Standard in a state's administrative code may vary from accrediting authority to accrediting authority. Several attendees suggested alternate formats to highlight the portions of the standard proposed for accelerated implementation.

STRATEGIC VISION FOR ELAB

Mr. Peter Spath and Dr. Billets reviewed recent discussions with representatives from other U.S. EPA-sponsored federal advisory committees. As a result of that meeting ELAB set aside time in their April 24, 2001 meeting to discuss the strategic vision for ELAB. Dr. Billets reported that there is a renewed effort from U.S. EPA to improve communication between FACA committees. He noted that the time, synchronous with the rechartering of ELAB and the first NELAP accreditation of laboratories, seems appropriate to address strategic vision for ELAB. U.S. EPA is committed to work to improve understanding of the role of the federal advisory committee in U.S. EPA and of how the advisory committee impacts the agency. U.S. EPA will also attempt to increase the impact of the federal advisory committee on the agency. In return each federal advisory committee must initiate and discuss the activities of the committee itself. Dr. Billets noted that the issue will be further discussed in ELAB's next meeting.

OTHER BUSINESS

Mr. Parr informed ELAB and the audience that he is forming a 501 (c) (3) nonprofit organization to assist NELAC with administrative issues. To that end he has drawn up articles of incorporation to be filed in the coming week and draft by-laws. He has also assembled a Board of Directors. In response to a question from the floor, Mr. Parr reported that he would serve as chair of the organization and that he would report to its Board of Directors.

OPEN FORUM ISSUES

With little time remaining in their allotted meeting time, the members of ELAB briefly reviewed issues raised at the Open Forum held on May 22, 2001. The issues and their disposition is summarized below:

1. Proposed changes to NELAC Standard may greatly impact data quality.
 - Change to "technology" should include various sample prep procedures
 - Pay attention to interchange between Chapters 1, 2, and 5 with regard to laboratory control samples (LCS), spiking analytes, PTs for analytes, etc.

- “Record-keeping” requirement of Chapter 5 requires laboratories to keep records but not to do anything with them
- Proper use of initial demonstration of capability

This issue was deferred for discussion in ELAB’s next teleconference.

2. PT Issues - PT programs as established seem to lack direction.

Noting extensive discussion on this issue in this meeting, ELAB deemed the issue complete.

3. Clarification of effective implementation date of approved NELAC Standard

- For future issues
- For 1999, 2000 approved standards

Noting that Ms. Hankins had presented the policy on implementation in this meeting, ELAB deemed the issue complete.

4. Impact of ISO 17025 revisions on NELAC Standard (especially Chapter 5)

Noting extensive discussion on this issue in this meeting, ELAB deemed the issue complete.

5. DOT/Shipping issues (pH) still a concern - commenter asked for update

Noting that Mr. Friedman had given an update during the Open Forum, ELAB deemed the issue complete.

6. Consistency issues based on interpretation of methods; “Local Interpretations” of procedure-specific implementation (e.g. t_0 for sample initiation, especially in the case of composite samples) *Is this a NELAC issue or an agency issue?*

This issue was deferred for discussion in ELAB’s next teleconference.

CONCLUSION

Members of U.S. EPA-sponsored advisory committees established under FACA are appointed for two-year terms and may serve no longer than six years. It was noted that Dr. Hershey and Mr. Verstuyft are departing ELAB after six years of service. On behalf of ELAB Dr. Verstuyft saluted Dr. Hershey for his service to ELAB and his impact on NELAP over the past six years. In response Dr. Hershey recognized all the members of ELAB and its subcommittees for their hard work over the past six years. On behalf of U.S. EPA Ms. Hankins presented both Dr. Hershey and Dr. Verstuyft with letters of thanks from Dr. John Lyon of U.S. EPA’s National Environmental Research Laboratory

(NERL) in Las Vegas. There being no further business to discuss the meeting was adjourned by Dr. Billets shortly before 5:00 p.m. MDT. ELAB's next meeting will be held on June 27, 2001 via teleconference.

**ACTION ITEMS
ENVIRONMENTAL LABORATORY ADVISORY BOARD
MAY 24, 2001**

Item No.	Action	Date to be Completed
1.	ELAB will recommend that NELAC establish a policy as to when it will develop standards for new testing areas such as source emissions, field sampling, etc. That policy should specify the number of requests necessary from federal agencies or accrediting authorities so that committees have a clear mandate to develop new standards.	Completed (NELAC 7)
2.	ELAB will consider the following suggestions offered at NELAC 7 regarding PT issues: <ol style="list-style-type: none">1. ELAB could make recommendation that a uniform scope of accreditation (especially for NELAC laboratories) be implemented as soon as possible.2. ELAB could make recommendation that non-NELAC states review NELAC PT program before developing their own programs.3. ELAB could encourage states to set only PT requirements rather than a fixed timeframe for PT sample analysis	June 27, 2001
3.	ELAB will consider recommendation to NELAC committees to remove the phrase "performance based measurement system" and the acronym "PBMS" from their chapters.	June 27, 2001
4.	ELAB will recommend that NELAC delay adoption of accreditation standards for stack testing for two years. ELAB recognizes the Field Activities Committee's concern for the quality of source testing and reporting data. In lieu of accreditation under the NELAC process, the states and U.S. EPA are, of course, free to promulgate regulations as they deem appropriate.	Completed (NELAC 7)
5.	ELAB will recommend that ASETT and the Measurement of Source Emissions (MSE) Subcommittee be disbanded as subcommittees of ELAB and the NELAC Field Activities Committee, respectively.	Completed (NELAC 7)
6.	ELAB will consider establishing liaison relationship with MDCB. (Jerry Parr, Bart Simmons)	June 27, 2001

ACTION ITEMS (CONTINUED)
ENVIRONMENTAL LABORATORY ADVISORY BOARD
MAY 24, 2001

Item No.	Action	Date to be Completed
7.	ELAB will consider endorsement of MDCB position paper recommendations. (Jerry Parr to customize specific issues of overlap between ELAB and MDCB and draft specific recommendation(s) for discussion at future ELAB meeting)	June 27, 2001
8.	ELAB will endorse all proposed changes to the NELAC Standard and recommend to the NELAC community that they vote to adopt them.	Complete (NELAC 7)
9.	ELAB will consider recommendation that NELAC BoD and U.S. EPA seek ways to reach out to other organizations to indicate that the scope of NELAC as defined in the NELAC Constitution includes non-laboratory organizations. (Jerry Parr and Allen Verstuyft to draft specific recommendation for discussion at future ELAB meeting)	June 27, 2001
10.	ELAB will include strategic vision on its agenda for upcoming meeting(s).	June 27, 2001

ACTION ITEMS (CONTINUED)
ENVIRONMENTAL LABORATORY ADVISORY BOARD
MAY 24, 2001

Item No.	Action	Date to be Completed
11.	<p>ELAB will include the following issues, raised at the May 22, 2001 ELAB Open Forum, on its agenda for upcoming meeting(s):</p> <ol style="list-style-type: none">1. Proposed changes to NELAC Standard may greatly impact data quality.<ul style="list-style-type: none">• Change to “technology” should include various sample prep procedures• Pay attention to interchange between Chapters 1, 2, and 5 with regard to laboratory control samples (LCS), spiking analytes, PTs for analytes, etc.• “Record-keeping” requirement of Chapter 5 requires laboratories to keep records but not to do anything with them• Proper use of initial demonstration of capability2. Consistency issues based on interpretation of methods; “Local Interpretations” of procedure-specific implementation (e.g. t_0 for sample initiation, especially in the case of composite samples) <i>Is this a NELAC issue or an agency issue?</i>	June 27, 2001
12.	ELAB will meet via teleconference.	June 27, 2001

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Environmental Laboratory Advisory Board (ELAB) Meeting

Thursday, May 24, 2001
2:00 – 5:00 p.m. (MDT)
Salt Lake City, Utah

AGENDA

1. Review minutes, action items
2. Present recent recommendations
3. PT report
4. Subcommittee reports as appropriate
5. Consider endorsement of MDCB recommendations (Jerry Parr)
6. Quality Systems PBMS Summary (Harry Gearhart)
7. Comments on standards being put forward for a vote at NELAC VII
8. Strategic vision for ELAB (Steve Billets, Peter Spath)
9. Open forum issues as time permits
10. Other business

